Informed Consent Directions:

Suggested headings for the consent form are **bold**.

Instructions about information to be provided are in plain type; consult §116 and §117 of the [Revised Federal Policy](#) for additional information about informed consent.

Examples of language a researcher might use in a consent form have the “Sample” watermark. These examples are often shorter than what may be necessary to fully describe your study. If assurances mentioned in the samples cannot be made for your study, the limitations and related risks for participants should be fully explained.

The beginning of the consent form should include a concise explanation, in easily understood language, of:

1. the fact that consent is being sought for research and that participation is voluntary.

2. the purpose and procedures of the research and how much time altogether this will require from the participant.

3. reasonably foreseeable risks or discomforts to the participant.

4. reasonably expected benefits for the participant or others; and

5. alternative procedures or treatments, if any, that might be advantageous to the participant.
Consent to Participate in Research

- You have been asked to volunteer for this research because you, a relative or friend of yours has been told they have breast cancer. You can choose to participate or choose not to participate. Either way, you will not give up any of your rights or benefits.

- The researchers are studying factors that may be related to having breast cancer and to what treatments are most successful. You will be asked to answer questions about your background, lifestyle, and physical and mental health. This will take about 45 minutes. You will also be asked to give researchers permission to see your medical records.

- Although researchers will try to protect your information, there is a possibility that health information, including genetic information, might become known to others. Information that could identify you will be separated from the rest of your data and stored separately.

- You will not benefit directly from participating in this research. Other cancer patients may benefit if new knowledge is gained from the study.

- This study only gathers information. It does not provide any treatments. Your alternative is to not participate.

Project Title: Risk Factors for Breast Cancer
Principal Investigator: Ellen Brighthouse, Ph.D.
Institution Conducting the Research: UCSF Medical Center

1. Purpose and Procedures of the Study

The goal of this study is to better understand the risk factors for breast cancer and how they relate to what treatments are most successful. You have been asked to participate because you, a relative or friend of yours has been told they have breast cancer. About ______ people from the ______ area will take part in this study. Half of them will be women who have had breast cancer. The other half will be relatives or friends of women who have had breast cancer. If you have had breast cancer, we will ask for permission to see your medical records. You will be required to sign a separate document that allows us to do this. That document explains how your protected health information will be used in the research, who else will have access to that information, and how long the authorization will last. All participants will be asked to answer survey questions about your background (such as racial or ethnic group), lifestyle (such as eating habits), and physical and mental health (such as intense feelings of sadness). This will take about 45 minutes.
2. Risks for Participants

Some of the health survey questions ask for very personal information, such as ______, but you don’t have to answer any questions you don’t want to answer. Your medical records include not only information related to the presence or absence of breast cancer, but also information about other aspects of your health, including genetic information. The researchers have extensive procedures designed to protect your privacy. They will separate any information that identifies you from the rest of your data and store those identifiers separately. Results used for analysis will not include your name or other identifiers. However, if some of the information about you were to become available to others, it could affect things like employability or access to insurance for you or your family.

3. Measures to Ensure Confidentiality

Any information about you that includes your identity will be kept confidential and will only be disclosed with your permission. The risk of releasing your information by mistake is small, but the researchers cannot guarantee that this will never happen. Your data will not be shared with other researchers. Results of the research may be presented at scientific or professional meetings or published in scientific journals. You will not be identified by name in any of those reports.

4. Benefits for Participants

You will not personally benefit from participating in this research. The investigators hope the results will lead to a better understanding of why women get breast cancer, how it develops, and how it is best treated.

5. Cost to Participants

There is no cost to you or to any insurance you may have for participating in this study.

6. Compensation for Participation

A $20 gift card will be mailed to you for answering the health survey questions.

7. Treatment and Compensation for Injury

If you were to experience a physical injury from the research procedures, appropriate medical treatment will be provided by UCSF. However, financial compensation is not available. For information or to report an injury, contact the Principal Investigator, Ellen Brighthouse.

8. Possibility for Conflict of Interest

The costs of this study are being paid by the UCSF Medical Research Foundation. The researchers do not have any financial incentives or conflicts of interest.
9. For Questions about this Study

If you have questions about this research, please contact the Principal Investigator, Ellen Brighthouse, at (415) 123-4567 or by email at ellen.brighthouse@ucsf.zzz. You may also ask the UCSF Institutional Review Board about your rights as a research participant. Their phone number is (415) 123-7689 or send email to irb@ucsf.zzz.

10. Your Participation is Voluntary

It is entirely your choice whether or not to participate in this research. You may stop participating at any time. You don’t have to answer any questions you prefer not to answer. You don’t have to sign any document you don’t want to sign. You will not lose any rights or benefits by choosing to participate or not to participate.

11. Participant’s Bill of Rights

A summary of your rights as a research participant is attached to this consent form.

12. Signature for Consent

I agree to participate in this research and have received a copy of the Participant’s Bill of Rights for Medical [or Non-Medical] Research.

_________________________     _________________________     _________________________
Printed Name of Participant          Signature of Participant                  Date Signed

_________________________    _________________________     _________________________
Printed Name of Representative   Signature of Representative          Date Signed
Additional Information for Researchers

Regarding item 1 in the consent form, the revised Federal Policy asks for identification of any procedures that are experimental. If any procedures or treatments are not considered, for example, to be standard, established, or commonly accepted for the research situation, this needs to be explained to participants. Of course, researchers will generally not want to use the word "experimental" to describe other manipulations of the research situation, as this would bias the behavior of participants.

Regarding item 3 in the consent form, an alternative disclosure about confidentiality might look like this:

Any information about you that includes your identity will be kept confidential and will only be disclosed with your permission. The risk of releasing your information by mistake is small, but the researchers cannot guarantee that this will never happen. Results of the research may be presented at scientific or professional meetings or published in scientific journals. You will not be identified by name in any of those reports. After they have removed information that identifies you, the researchers may use your data in other research without your further consent, and they may also share your data with other researchers without your further consent. You should be aware that any data, and especially genetic information, may become identifiable in the future despite what the researchers do to remove information about you.

The revised Federal Policy lists the following additional elements that are to be provided in the consent form when appropriate:

1. A statement that the research procedures may involve unforeseeable risks to the participant (or to the embryo or fetus, if pregnant).
2. Circumstances under which the participant’s participation may be terminated by the investigator.
3. Consequences of a decision to withdraw from the research, and the procedures for doing so.
4. A statement that significant new findings which might affect willingness to participate will be provided if they occur.
5. The approximate number of participants in the study.
6. A statement that biospecimens (even if de-identified) may be used for commercial profit and whether the participant will share in those profits.
7. Under what conditions any clinically relevant results, including individual results, will be disclosed to participants.
8. Whether research with biospecimens will or might include whole genome sequencing.